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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,549	08/03/2001	Jeffrey C. Rapp	AVI 013	1388

7590 01/29/2004  
PENNIE & EDMONDS LLP  
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NEW YORK, NY 10036-2711

EXAMINER

LEFFERS JR, GERALD G

ART UNIT

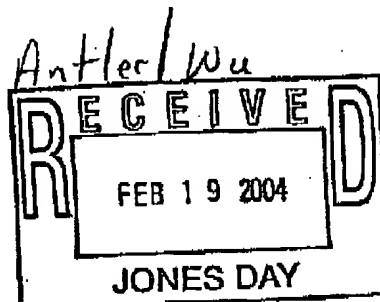
PAPER NUMBER

1636

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.-----

Amendment (Final Action) 4.29.04



PTO-90C (Rev. 10/03)

**Office Action Summary****Application No.**

09/922,649

**Applicant(s)**

RAPP, JEFFREY C.

**Examiner**

Gerald G Leffers Jr., PhD

**Art Unit**

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8, 11-22, 25-33, 37-44 and 59-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 11-22, 25-33, 37-44 and 59-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11/5/03. 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Receipt is acknowledged of an amendment, filed 11/6/2003, in which several claims were amended (8, 11-12, 14-15, 17-29, 31-33, 37, 42, 44, 59, 61), several claims were cancelled (claims 9-10, 23-24 and 58) and in which several new claims were added (claims 62-69). Claims 8, 11-22, 25-33, 37-44 and 59-69 are pending and under consideration in the instant application.

Any rejection of record in the previous office action, mailed 05/07/2003, not addressed herein is withdrawn. This action is FINAL as the new grounds of rejection made herein were necessitated by applicant's amendment filed 11/6/2003.

### *Election/Restrictions*

In the response filed 11/6/2003 it is asserted that claims 37-39 and 42-44 are linking claims. This assertion is inaccurate in that the originally filed claims encompassed both *in vivo* and *in vitro* embodiments. Applicants have amended the claims to only encompass the *in vitro* embodiments (i.e. an isolated cell). Therefore, the claims are no longer considered to be linking claims encompassing both *in vivo* and *in vitro* embodiments.

### *Information Disclosure Statement*

Receipt is acknowledged of an information disclosure statement filed 11/6/2003. The signed and initialed PTO Form 1449 has been mailed along with this action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 11-22, 25-33, 37-44 and 59-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in Paper No. 14, mailed 5/7/2003.**

#### *Response to Arguments*

Applicant's arguments filed in the paper filed 11/6/2003 have been fully considered but they are not persuasive. The response essentially argues that amendment of the claims to be directed solely to recombinant DNA molecules and cells comprising a lysozyme gene expression control region where elements (a)-(g) are obtained from a chicken, and deleting reference to "degenerate variants" thereof, has obviated the grounds for the rejection.

The response is not persuasive on at least two grounds. First, as written the claims continue to encompass embodiments featuring a hybrid lysozyme gene expression control region where each of the different elements (a)-(f) are obtained from chicken genes other than the lysozyme gene. Further, the claims continue to encompass embodiments that include variants of SEQ ID NO: 67 while specifying that the recombinant DNA must drive expression of an operatively linked and heterologous gene in chicken oviduct cells. There is insufficient description in the prior art and instant specification of the changes that can be made to SEQ ID NO: 67 and still retain the recited functionality. It would be remedial to amend the claim

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language to explicitly state stringent hybridization conditions that would provide a nexus between structural and functional characteristics of the claimed nucleic acids.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 11-22, 25-33, 37-44 and 59-69 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 11, 22, 37 are vague and indefinite in that the metes and bounds of the phrase "...wherein each of elements (a)-(g) is obtained from a chicken..." are unclear. It is unclear whether the amended claims are necessarily directed to a lysozyme gene expression control region where each of the recited elements (a)-(f) are obtained from the chicken lysozyme gene, or if the claims encompass elements where elements (a)-(f) may be obtained from alternative sources (i.e. other chicken genes). Upon reading the specification, it appears the cited term should be amended to read "wherein each of elements (a)-(g) is obtained from the chicken lysozyme gene". **This is a new rejection, necessitated by applicant's amendment of the claims in the response filed 11/6/2003.**

Claims 11, 14, 18, 25, 28, 32, 61-62 are vague and indefinite in that the metes and bounds of the phrase "highly stringent hybridization conditions" are unclear. The specification does address the issue of "highly stringent hybridization conditions", but does not explicitly state what the minimal requirements are in order to meet the limitation of being "highly stringent" (see pages 22-25 of the instant specification). It would be remedial to amend the claim language to

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include specific hybridization conditions for which there is explicit support in the specification.

**This is a new rejection, necessitated by applicant's amendment of the claims in the response filed 11/6/2003.**

Claims 8, 11, 22, 25, 37 and 62 recite the limitation of an "intrinsically curved" DNA region. This term does not appear to be explicitly defined in the specification or prior art. How "curved" does the DNA have to be in order to satisfy this limitation? Is there a functional definition (e.g. prevents binding of matrix proteins within a region) that is applicable and art recognized for the term? **This rejection is maintained for reasons of record and extended to claims 11, 25, 37 and 62 due to applicant's amendment of the claims in the response filed 11/6/2003.**

***Response to Arguments/112 2<sup>nd</sup> paragraph***

Applicant's arguments filed 11/6/2003 have been fully considered but they are not persuasive. The response essentially argues that the term "intrinsically curved DNA" is known in the art and cites GenBank Accession No. X52989 as evidence (see Table II on Page 65). This citation does not, however, provide a definition of what constitutes "intrinsically curved DNA".

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

Ggl

  
GERRY LEFFERS  
PRIMARY EXAMINER